Disinvestment of BHEL, HEC, etc.

3490. SHRI RAMA MUNI REDDY SIRIGIREDDY: Will the Minister of DISINVESTMENT be pleased to state:

(a) whether it is a fact that his Ministry has decided to disinvest Government's stake in five public sector undertakings namely BHEL, Heavy Engineering Corporation, Bharat Ophthalmic Glass Limited, HMT and Hindustan Photo Films Limited; and

(b) if so, the details thereof and the reasons therefor?

THE MINISTER OF DISINVESTMENT (SHRI ARUN SHOURIE): (a) and (b) On a reference by the Ministry of Heavy Industry and Public Enterprises, the process of disinvestment/Joint Venture formation in Bharat Ophthalmic Glass Limited has been taken up and it has not yet been completed. As of now, there is no proposal of disinvestment in Heavy Engineering Corporation. The information in respect of BHEL, HMT and Hindustan Photo Films Limited is being collected and will be laid on the Table of the House.

New drug permissions

3491. SHRI MUNNAVAR HASAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that DCGI office is using discretionary powers in granting new drug permissions;

(b) the details of number of applications received during 2001 for new drug permissions, Bio-equivalence permission;

(c) when were these applications received and the time taken for the final permission; and

(d) whether it is a fit case to be investigated by CBI?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA): (a) to (c) The following are the number of new drug applications received during the year 2001:

1. Investigational New Drug (IND)—2
2. New Drug Applications—56
3. Subsequent Applications for New Drug approval requiring Bio-equivalence studies about 400.

Applications for permission for clinical trials, Bio-equivalence studies and marketing of new drugs are examined by the New Drug Division in the office of DCG (I). The requirement for granting such approval are specified in Rules 122A, 122B, 122C, 122D and 122E and Schedule Y of Drugs and Cosmetics Rules. The evaluation of new drug/clinical trial is a complex process and varies according to the nature of molecule drug, published data and information furnished by applicants. Therefore, depending upon the nature of the application, it may take on an average more than 5 years for approval of investigation New Drug (*i.e.* a drug molecule not tested on human being anywhere in the world) about 1—3 years for the first time approval of the drug already approved elsewhere but requiring confirmatory clinical trial and about 2-3 months for subsequent applications for already approved drugs. This is, however, subject to submission of all required data as per provisions of Schedule Y of Drug and Cosmetics Rules. Certain critical drugs *e.g.* anti-cancer, anti-HIV etc. which are important from the point of view of public health are also cleared on a fast track basis. Permissions are granted after taking into account the technical requirements and not on discretion.

(d) The question of investigation by CBI does not arise.

Training for traditional birth attendants

3492. MISS MABEL REBELLO: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether a programme for training of traditional birth attendants has been launched in 142 districts in the country;

(b) the financial allocation for training of these *Daaces* in the year 2001-2002;

(c) whether Government are giving any honorarium to these *Daaees* for conducting safe delivery in the villages;

(d) whether there is any plan to give upgraded training to these *Daaees*; and

(e) if so, the names of 142 districts which have been selected for the programme?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A . RAJA): (a) During 2000-01, a scheme for training of traditional birth attendants was launched in 142 districts of the country, in which safe delivery rates were found to be less than 30 per cent. 14 more districts have been added during 2001-02.